K002951

DEC - 8 2000

ATTACHMENT G

510 (k) SUMMARY

The Magellan ventilator is a virtual duplicate of the predicate device, both of which were designed by the same individual. The only differences between the Magellan ventilator and the predicate device is that of the outer container, in terms of size and shape, neither of which affects the performance or substantial equivalence of the submitted device.

The predicate device has been in continuous production since 1988 with no reported failures in the field which adds credence to the proof of the original and Magellan ventilator's design and materials selection.

The intended use and design of the Magellan ventilator lends itself to assisting the breathing of patients requiring short-term artificial ventilation, especially in environments where normal hospital supplies and personnel are not always available.

The Magellan ventilator has been tested and found to be identical in performance and quality to its predicate. Oceanic Medical Products, Inc., believes that the Magellan ventilator will serve its patient population as well or better than the predicate device.

Due to the unique nature of the Magellan ventilator and its predicate device, the excellent history of the predicate device and both devices having been designed by the same person, we trust that the FDA will find the Magellan ventilator substantially equivalent, using minimal time and resources.

Oceanic Medical Products looks forward to receiving certification by the FDA of the Magellan ventilator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2000

Mr. William M. Gates
Oceanic Medical Products, Inc.
8005 Shannon Industrial Park Lane
Archison, KS 66002

Re: K002951
Magellan Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: September 20, 2000
Received: September 21, 2000

Dear Mr. Gates:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Oceanic Medical Products, Inc.

ATTACHMENT H

[redacted] INDICATIONS FOR USE

510(K) Number if known: K002951

Device Name: Magellan Ventilator

Indications for Use:

The Magellan Ventilator is intended to be used to deliver air or a mixture of air and oxygen, to a patient requiring the use of a mechanical ventilator, either in a hospital or, in an emergency transport situation.

(Division Sign-Off)
Division of Cardiovascular & Respiratory Devices
510(k) Number K002951

X PRESCRIPTION USE or ___ OVER-THE-COUNTER

8005 Shannon Park Lane, Atchison, KS 66002 Tel: 913 874 2000 fax: 913 874 2005